UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

REGENERON PHARMACEUTICALS, INC. Plaintiffs, vs. GENENTECH, INC., Defendant.	Civil Action No. 11-CV-01156 (VB) ECF Case Jury Demand

PLAINTIFF REGENERON PHARMACEUTICALS, INC.'S REPLY TO DEFENDANT GENENTECH, INC.'S AMENDED ANSWER AND COUNTERCLAIM

Plaintiff and Counterclaim Defendant Regeneron Pharmaceuticals, Inc. ("Regeneron"), by and through its undersigned counsel, replies as follows to the Amended Answer and Counterclaim of Defendant Genentech, Inc. ("Genentech"):

1–21. Paragraphs 1–21 of the Amended Answer and Counterclaim contain Genentech's responses to the Complaint filed by Regeneron on February 18, 2011 and therefore do not require a response from Regeneron. To the extent any allegations in paragraphs 1–21 of the Amended Answer and Counterclaim require a responsive pleading, Regeneron denies those allegations.

22. Regeneron denies the allegations in paragraph 22.

23. Regeneron denies that Genentech is entitled to reserve the right to assert and pursue additional defenses.

24. Paragraph 24 of the Amended Answer and Counterclaim contains Genentech's demand for a jury trial and therefore does not require a response from Regeneron.

25. Regeneron is informed of and believes the allegations in paragraph 25, and therefore admits them.

26. Regeneron admits the allegations in paragraph 26.

27. Regeneron admits that Genentech purports to bring a counterclaim in the form of an action for infringement under the patent laws of the United States of America, 35 U.S.C. § 1 *et. seq.* Regeneron denies each and every remaining allegation in paragraph 27. Regeneron specifically denies that Genentech's counterclaim has any factual or legal merit.

28. Regeneron does not contest personal jurisdiction in this Court for the purposes of this action.

29. Regeneron admits that venue is proper in this District.

30. Regeneron admits that United States Patent No. 5,952,199 (the "'199 patent"), on its face, is entitled "Chimeric Receptors as Inhibitors of Vascular Endothelial Growth Factor Activity, and Processes for Their Production," that it states it issued on September 14, 1999, and that it names Terri Lynn Davis-Smyth, Helen Hsifei Chen, Leonard Presta, and Napoleone Ferrara as inventors. Regeneron is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 30, and therefore denies each and every remaining allegation of paragraph 30.

31. Regeneron admits that United States Patent No. 6,100,071 (the "'071 patent"), on its face, is entitled "Receptors as Novel Inhibitors of Vascular Endothelial Growth Factor Activity and Processes for Their Production," that it states it issued on August 8, 2000, and that it names Terri Lynn Davis-Smyth, Helen Hsifei Chen, Leonard Presta, and Napoleone Ferrara as inventors. Regeneron is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 31, and therefore denies each and every remaining allegation of paragraph 31.

32. Regeneron admits that United States Patent No. 6,383,486 (the "'486 patent"), on its face, is entitled "Inhibitors of Vascular Endothelial Growth Factor Activity, Their Uses and Processes for Their Production" that it states it issued on May 7, 2002, and that it names Terri Lynn Davis-Smyth, Helen Hsifei Chen, Leonard Presta, and Napoleone Ferrara as inventors. Regeneron is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 32, and therefore denies each and every remaining allegation of paragraph 32.

33. Regeneron admits that United States Patent No. 6,897,294 (the "'294 patent"), on its face, is entitled "Inhibitors of Vascular Endothelial Growth Factor Activity, Their Uses and Processes for their Production," that it states it issued on May 24, 2005, and that it names Terri Lynn Davis-Smyth, Helen Hsifei Chen, Leonard Presta, and Napoleone Ferrara as inventors. Regeneron is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 33, and therefore denies each and every remaining allegation of paragraph 33.

34. Regeneron admits that United States Patent No. 7,771,721 (the "'721 patent"), on its face, is entitled "Methods for Using Chimeric Vascular Endothelial Growth Factor Receptor Proteins," that it states it issued on August 10, 2010, and that it names Terri Lynn Davis-Smyth, Helen Hsifei Chen, Leonard Presta, and Napoleone Ferrara as inventors. Regeneron is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 34, and therefore denies each and every remaining allegation of paragraph 34.

35. Paragraph 35 contains no factual allegations, and therefore does not require a response from Regeneron.

36. Regeneron is informed of and believes, and on this basis alleges, that Genentech is the owner of the Davis-Smyth patents. Regeneron is without knowledge or information

sufficient to form a belief as to the truth of the remaining allegations in paragraph 36, and therefore denies each and every remaining allegation of paragraph 36.

37. Regeneron admits that it has known about the Davis-Smyth patent family since at least May 9, 2005. Regeneron is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 37, and therefore denies each and every remaining allegation of paragraph 37.

38. Regeneron admits that the VEGF Trap-Eye product is a specially purified and formulated form of VEGF Trap, a protein-based product, for use in intraocular applications. Regeneron is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations in paragraph 38, and therefore denies each and every remaining allegation of paragraph 38.

39. Regeneron admits that its VEGF Trap-Eye product can bind VEGF-A along with Placental Growth Factor (PlGF) and that it is seeking approval for the product to be used to treat certain conditions in the eye that are believed to involve new blood vessel growth. Regeneron denies each and every remaining allegation in paragraph 39.

40. Regeneron admits that it has filed a BLA with the FDA regarding VEGF Trap Eye and has described this application as for marketing approval of VEGF Trap-Eye for wet age-related macular degeneration in the United States. Regeneron denies each and every remaining allegation in paragraph 40.

41. Regeneron admits that it has made or used, or is making or using, VEGF Trap-Eye in the United States. Regeneron admits that it has filed a BLA with the FDA seeking approval to market VEGF Trap-Eye in the United States. Regeneron denies each and every remaining allegation in paragraph 41.

42. Regeneron admits that, within this judicial district, it has taken concrete and substantial steps to prepare for commercial manufacturing and marketing of VEGF Trap-Eye. Regeneron denies each and every remaining allegation in paragraph 42.

43. Regeneron admits the allegations in paragraph 43.

44. In response to the allegations in paragraph 44, Regeneron incorporates its responses to paragraphs 25–43 set forth above as if fully set forth herein.

45. Regeneron denies the allegations in paragraph 45.

46. Regeneron denies the allegations in paragraph 46.

47. Regeneron denies the allegations in paragraph 47.

48. Regeneron denies the allegations in paragraph 48.

49. In response to the allegations in paragraph 49, Regeneron incorporates its responses to paragraphs 25–48 set forth above as if fully set forth herein.

50. Regeneron denies the allegations in paragraph 50.

51. Regeneron denies the allegations in paragraph 51.

52. Regeneron denies the allegations in paragraph 52.

53. Regeneron denies the allegations in paragraph 53.

54. In response to the allegations in paragraph 54, Regeneron incorporates its responses to paragraphs 25–53 set forth above as if fully set forth herein.

55. Regeneron denies the allegations in paragraph 55.

56. Regeneron denies the allegations in paragraph 56.

57. Regeneron denies the allegations in paragraph 57.

58. Regeneron denies the allegations in paragraph 58.

59. In response to the allegations in paragraph 59, Regeneron incorporates its responses to paragraphs 25–58 set forth above as if fully set forth herein.

60. Regeneron denies the allegations in paragraph 60.

61. Regeneron denies the allegations in paragraph 61.

62. Regeneron denies the allegations in paragraph 62.

63. Regeneron denies the allegations in paragraph 63.

64. In response to Genentech's Prayer for Relief, Regeneron denies that Genentech is entitled to any relief sought in paragraphs 1–7 of its Amended Counterclaim.

DEFENSES

Regeneron asserts the following defenses to Genentech's Amended Counterclaim. Assertion of a defense is not a concession that Regeneron has the burden of proving the matter asserted.

First Defense (Failure To State A Claim)

65. Genentech's claims are barred in whole or in part because Genentech has not stated a claim upon which relief can be granted.

Second Defense (Non-Infringement)

66. No acts by any entity related to the VEGF Trap have infringed, infringe, or will infringe any valid claim of the Davis-Smyth patents.

Third Defense (Invalidity)

67. The claims of the Davis-Smyth patents are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112 and general principles of patent law.

Fourth Defense (Laches And Unclean Hands)

68. Genentech is precluded from recovering on its claims for relief pursuant to and/or its patents are invalid or unenforceable pursuant to the doctrines of laches and/or unclean hands, including because of its delays during prosecution of the Davis-Smyth patents and its delay and attempted delay in the presentation of its claims.

Fifth Defense (Estoppel)

69. Genentech is estopped, including by its delay and attempted delay in the presentation of its claims, and by cancellations, amendments, representations, and concessions made to the United States Patent and Trademark Office during the prosecution of the Davis-Smyth patents and/or the prosecution of any applications or patents from which the Davis-Smyth patents claim priority, from construing any claim of the Davis-Smyth patents to have been infringed by any acts by any entity involving the VEGF Trap.

DEMAND FOR JURY TRIAL

Regeneron demands a trial by jury on all issues in this case properly tried to a jury.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff and Counterclaim Defendant Regeneron prays for judgment as follows on Genentech's Amended Counterclaim:

A. That Genentech's Amended Counterclaim be dismissed with prejudice and that Genentech take nothing by reason of its Amended Counterclaim;

B. Judgment in Regeneron's favor on all claims for relief;

C. A declaration that no acts by any entity involving VEGF Trap do or will directly or indirectly infringe any valid claim of the Davis-Smyth patents;

D. A declaration that this case is exceptional pursuant to 35 U.S.C. § 285, and an award of attorneys' fees and costs; and

E. For an award of such other and further relief as the Court may deem just and proper.

Dated: May 25, 2011

FITZPATRICK, CELLA, HARPER & SCINTO

By: _/s/Brian Slater_____

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